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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/776,109

02/11/2004

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EXAMINER

TANNER, JOCELYN C

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/776,109	<b>Applicant(s)</b> KHEIRI, MOHAMMAD A.	
	<b>Examiner</b> JOCELIN C. TANNER	<b>Art Unit</b> 4133	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 2/11/2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 2/11/2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/25/2004</u> .   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

This is in response to the application filed on February 11, 2004 in which claims 1-19 are presented for examination.

#### ***Status of claims***

Claims 1-19 are pending, of which 1, 6 and 11 are in independent form. Claims 1,2, and 4-5 are rejected under 102(e) and claims 3 and 6-19 are rejected under 103(a).

#### ***Information Disclosure Statement***

1. The information disclosure statement (IDS) submitted on 8/25/2004 was filed after the mailing date of the Patent Application on 2/11/2004. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

#### ***Drawings***

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: 1228 and 1230. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be

notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: 1131. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1, 2 and 4-5 are rejected under 35 U.S.C. 102(e) as being anticipated by Sharma et al (US Patent No. 6,491,709).

6. With respect to claim 1, Sharma discloses an endcap for a lancing device comprising "a body" in column 2, lines 25-26 and 38-40. A "contact face on said body" is disclosed by Sharma in column 2, lines 35-41 by referring to a cap tip attached to the body of the lancer device that will have surface contact. Sharma teaches "an opening in the said contact face" in column 3, lines 50-53 and in FIGS. 3-4, #105, where an aperture is shown through which a stylet of a lancet can extend. Also disclosed is "a pattern of pressure points on said face, wherein said pressure points comprise a pattern of a plurality of ribs with channels defined between adjacent ribs" in column 3, lines 24-26. The multiple crenellations that extend from the distal end of the lancer device can be regarded as a pattern of ribs that form pressure points. The crenellations are small ridges that cause pressure when placed upon a contact surface. The depressions are grooves that separate each crenellation as do the channels that reside between each rib. The depressions, like the channels, do not cause pressure.

7. Most of the limitations of dependent claim 2 have been discussed in the rejection of claim 1 above. In addition, Sharma discloses a body being formed of "transparent material" in column 3, lines 20-23, so as to permit the expressed blood to be viewed through the endcap.

8. Most of the limitations of dependent claim 4 have been discussed above in the rejection of claim 1. Sharma additionally discloses pressure points that are "concentric" with the opening of the endcap in FIG 3, #100. The crenellations are pressure points and have a common center surrounding the aperture.

9. Most of the limitations of dependent claim 5 have been discussed above in the rejection of claim 1. Furthermore, Sharma teaches "radially" extending pressure points in FIG 1, #100, in which the crenellations are arranged outwardly from a central opening.

***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 3 and 6-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moerman et al (US Patent No. 6,706,049) in view of Sharma et al (US Patent No. 6,491,709).

Most of the limitations of claim 3 have been noted in the above rejection of claim 1. However, Sharma does not disclose a contact face that is "concave".

Moerman discloses a contact ring, the "contact face" of the cap body, being concave in curvature in column 5, lines 35-45.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention, having the teachings of Moerman and Sharma, to form a concaved contact face that would cause a decrease in pressure as the contact face extends inwardly and towards the opening, thus initiating a pressure gradient that will cause fluid to flow towards the opening (Moerman, column 6, lines 1-5). This method for improving the endcap of Sharma was within the ordinary ability of one of ordinary skill in the art based on the teachings of Moerman.

12. With respect to independent claim 6, Sharma teaches an “endcap” for a lancing device comprising “a body, said body including a face, an aperture, in said face for passage of a lancet, said face being concave, and a rib pattern on said face”. “A body” that includes a “face” is disclosed in column 2, lines 35-41 and 38-40, in which the body of the endcap is the nose portion and the face is the cap tip. “An aperture” is taught in column 3, lines 50-53 and in FIGS 3-4, #105, in which a stylet on the lancet may extend through the aperture to make a puncture. A “rib pattern” is disclosed in column 3, lines, 23-26, FIG 3, #101, #102, in which multiple crenellations extend from the distal end of the cap creating a distinctive design.

The difference between Sharma and claim 6 is the recitation of a concave contact face.

Moerman discloses a contact ring, the contact face of the cap body, being concave in curvature in column 5, lines 35-45.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention, having the teachings of Moerman and Sharma, to form a concaved contact face because it would cause a decrease in pressure as the contact face extends inwardly and towards the opening thus initiating a pressure gradient that will cause fluid to flow towards the opening (Moerman, column 6, lines 1-5). This method for improving the endcap of Sharma was within the ordinary ability of one of ordinary skill in the art based on the teachings of Moerman.

13. Claim 7 is dependent upon independent claim 6, which has been rejected as discussed supra with respect to Sharma and Moerman. Additionally, Sharma discloses a "rib pattern" which includes a "plurality of ribs" in column 3, lines 23-26, FIG 3, #101 and #102. Crenellations or fingers that extend from the distal end of the site tip may be regarded as a pattern of ribs for the crenellations create a distinctive design. The depressions that separate the crenellations are gaps between each crenellation and therefore may be defined as channels. A "plurality of ribs" is displayed in FIG 3, #101 and #102, where more than one crenellation is shown.

14. Claim 8 is dependent upon independent claim 6, which has been rejected as discussed supra with respect to Sharma and Moerman. Moreover, Sharma discloses a body being formed of "transparent material" in column 3, lines 20-23.



15. Claim 9 is dependent upon independent claim 6, which has been rejected as discussed supra with respect to Sharma and Moerman. Sharma also teaches “pressure points” that are "concentric" with the opening of the endcap in FIG 3, #100. The crenellations have a common center and cause pressure when placed upon a surface.

16. Claim 10 is dependent upon independent claim 6, which has been rejected as discussed supra with respect to Sharma and Moerman. Sharma teaches “radially” extending pressure points in FIG 1, #100, in which the crenellations are arranged outwardly from a central opening.

17. Claims 11-15, 17 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sharma et al (US Patent No. 6,491,709) and Douglas et al (US Patent No. 6,332,871).

With respect to independent claim 11, Sharma discloses a “lancing device” with a “lancet” and an “endcap” in column 2, lines 18-26 as well as in column 3, lines 47-53 in which the cap tip being the endcap. A “skin contacting face with a pattern of pressure points” is taught by Sharma in column 3, lines 23-26 and FIG 3 and also discussed in the rejection of claim 1. Placing the “contact face onto a selected site” and “actuating said lancet to puncture skin”, is disclosed by Sharma in column 1, lines 33-34.

The difference between Sharma and claim 11 is the recitation of "massaging" the site with the contact face to cause blood to flow to the puncture site.

Douglas discloses a “method of drawing a blood sample” by “massaging” the site with the contact face to cause blood to flow to the puncture site in column 5, lines 57-63.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention, having the teachings of Douglas and Sharma, to apply frictional movement of the contact face to the puncture site to cause fluid to expel toward the incision.

18. Claim 12 is dependent upon independent claim 11, which has been rejected as discussed supra with respect to Sharma and Douglas. Additionally, Douglas teaches the method of “massaging” the site “prior to actuating the lancet” in column 5, lines 57-58.

19. Claim 13 is dependent upon independent claim 11, which has been rejected as discussed supra with respect to Sharma and Douglas. “Alternating turning” the endcap “clockwise and counterclockwise while maintaining pressure” is disclosed by Sharma in column 3, lines 27-31 and lines 40-45. Twisting and rotating the endcap can occur in both directions.

20. Claim 14 is dependent upon independent claim 11, which has been rejected as discussed supra with respect to Sharma and Douglas. “Rocking” is disclosed by Douglas in column 5, lines 57-60, in which blood flow is enhanced through massaging the puncture site. Rocking can be defined as a type of massaging that encompasses rubbing the endcap back and forth or side to side to stimulate circulation.

21. Claim 15 is dependent upon independent claim 11, which has been rejected as discussed supra with respect to Sharma and Douglas. "Toward and away" is disclosed by Douglas in column 5, lines 57-60, in which blood flow is enhanced through massaging the puncture site. Toward and away can be defined as a type of massaging that encompasses rubbing the endcap to and from the puncture site.

22. Claim 17 is dependent upon independent claim 11, which has been rejected as discussed supra with respect to Sharma and Douglas. Moreover, Sharma discloses "channels in the contact face" that are defined through the formation of "pressure points" in column 3, lines 23-26 and FIG 3, #102. The "channels" can be described as depressions separated by the crenellations that do not apply pressure when applied to a surface.

23. Claim 19 is dependent upon independent claim 11, which has been rejected as discussed supra with respect to Sharma and Douglas. Sharma additionally discloses a "transparent" endcap that allows the "viewing" of the amount of blood that has been extracted from the puncture site "while massaging" in column 3, lines 20-21.

24. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sharma et al (US Patent No. 6,491,709) in view of Douglas et al (US Patent No. 6,332,871) as

applied to claim 11 above, and further in view of Levaughn et al (US Patent No. 6,283,982).

With respect to dependent claim 16, Sharma and Douglas do not recite the method of "applying constant pressure" to the skin using the contact face.

Levaughn discloses a method of applying a steady, compressive pressure after initiating the puncture in order to stimulate the flow of fluid in column 11, lines 19-30.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention, having the teachings of Douglas, Sharma and Levaughn, to use a compressive force to create a tension in the tissue that would cause the wound to open and fluid flow to commence. This method of improving the procedure of expelling fluid in Sharma and Douglas was within the ordinary ability of one of ordinary skill in the art based on the teachings of Levaughn.

25. Claim 18 rejected under 35 U.S.C. 103(a) as being unpatentable over Sharma et al (US Patent No. 6,491,709) and Douglas et al (US Patent No. 6,332,871) as applied to claim 11 above, and further in view of Moerman et al (US Patent No. 6,706,049).

With respect to dependent claim 18, the difference between Sharma and Douglas and claim 18 is the recitation of the method comprising of "beveling" contact face around the aperture which would provide the "reduction of pressure" toward the aperture as the site is massaged by the contact face.

Moerman discloses an aperture with a "beveling" contact face in column 5, lines 40-45 and column 6, lines 47-49. The beveling of the contact face is described by the

slanting and incline formed by the concavity of the contact face. In turn, the concavity causes a "reduction of pressure" toward the aperture as the site is massaged by the contact face in, column 6, lines 7-15.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention, having the teachings of Douglas, Sharma and Moerman, to form a decreasing pressure gradient to urge the fluid to flow toward the aperture thus creating a smooth, not turbulent, release of fluid at puncture site.

### ***Conclusion***

26. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Douglas et al (US Patent No. 5,951,493), Duchon et al (US Patent No. 5,879,311) and Duchon et al (US Patent No. 6,464,649) relate to lancing devices and methods for obtaining samples of blood and other fluids.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOCELIN C. TANNER whose telephone number is (571)270-5202. The examiner can normally be reached on Monday through Thursday between 9am and 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frantz Coby can be reached on 571-272-4017. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 4133

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jocelin C. Tanner/  
Examiner, Art Unit 4133

1/08/2008

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